



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,121	01/17/2002	Cato T. Laurencin	DRE-0067	1682

7590

04/01/2005

Licata & Tyrrell P.C.
66 East Main Street
Marlton, NJ 08053

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,121

Applicant(s)

LAURENCIN ET AL.

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment of 1/10/05 amended the specification and claims 1, 3 and 6.

Claims examined on the merits are 1-3, 5 and 6, which are all
5 claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated
10 by Devin et al (document AE on PTO-1449) for reasons in the previous office action of 10/8/04 and for reasons herein.

The claim is drawn to scaffold for tissue engineering comprising a biodegradable polymer-based hollow microcarriers with a density equal to or less than water bonded together into an interconnected,
15 three dimensional scaffold.

Devin et al disclose degradable polymer-ceramic 3-dimensional composite matrices for use as a bone graft material. The matrices are porous and are an aggregate of polymeric microspheres (page 662, second paragraph under "Matrix fabrication" and page 663, under
20 "RESULTS).

The matrices obtained by Devin et al are a scaffold as presently claimed. The microspheres of the aggregates appear to be hollow as evidenced by Figure 2, and due to being hollow and having porosity between the microspheres of the aggregates, the matrices of Devin et
25 al inherently have a density less than the density of water.

Response to Arguments

Applicant's arguments filed 1/10/05 have been fully considered but they are not persuasive.

Applicants urge that Devin et al do not produce hollow polymer-
5 based microcarriers or methods adapted for their production.

This argument is unpersuasive since the method used by Devin et al produces an aggregate of polymeric microspheres. The microspheres can be considered microcarriers, and designating the microspheres of Devin et al as microcarriers does not make the microcarriers of the
10 claims different from the microspheres. Figure 2 of Devin et al (page 664) shows the microspheres as hollow. This results from an emulsion being formed by combining a solution of 50:50 PLAGA dissolved in chloroform with a solution of PVA in water (page 662, 5th complete paragraph), and drying. This type of procedure is used in Example 1
15 of the present specification (page 14) where 50:50 PLAGA is dissolved in methylene chloride, and the resultant solution is added to a solution of PVA followed by separating microcarriers, which are dried and subsequently bonded together (Example 2). The microcarriers obtained are microspheres, and bonding the microcarriers together
20 results in an aggregate as obtained by Devin et al. Even if the bonded together microcarriers resulting from Examples 1 and 2 in the specification are different from the aggregates of Devin et al, it is uncertain as to what this difference would be, and the claims do not require a difference. The aggregates of Devin et al contain the
25 microspheres bonded together, which results in an interconnected

Art Unit: 1651

network. Due to the microspheres being hollow as shown by Figure 2 as a result of an emulsion being formed, and having porosity due to channels between the microspheres, the aggregates of Devin et al will inherently have a density less than that of water.

Claim Rejections - 35 USC § 103

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devin et al in view of Spaulding (6,001,643) and Granet et al (AJ on 1449), and if necessary in further view of Kusano et al (5,006,467), Henderson (4,448,884) or Starling et al (6,210,715 B1) for reasons in the previous office action and for reasons herein.

Claims 5 and 6 require seeding the scaffold of claim 1 with cells and culturing *in vitro* in a rotating bioreactor.

Devin et al is described above.

Spaulding discloses culturing cells in a roller bottle for implanting to produce tissue. Microcarrier beads having densities less than the cell culture medium can be used for cell attachment to constrain tissue constructs to the area surrounding the annular axis and away from the cylinder wall of the bottle (col 16, lines 25-30).

Granet et al disclose culturing osteoblastic cells on microcarriers in a rotating-wall vessel (page 514, section 2.1.2).

It would have been obvious to use the matrices of Devin et al for cell culture in a roller bottle as disclosed by Spaulding or in a rotating-wall vessel as disclosed by Spaulding since these culturing techniques are intended for culturing cells on a carrier. It would have been further obvious to provide the matrices with a density less

than or equal to that of water as suggested by Spaulding so the matrices will surround the axis away from the wall. If needed Kuşano et al (col 2, line 66), Henderson (col 2, line 12) or Starling et al (col 6, lines 59-61 and col 10, line 38) would have further suggested
5 a density equal to that of water from disclosing cell culture with a microcarrier having a density of 1 g/ml or 1 g/cc. Culturing of osteoblast cells would have been obvious and if needed suggested by Granet et al since these cells produce bone as desired by Devin et al.

Response to Arguments

10 Applicants rely on the argument above that Devin et al does not obtain hollow polymer-based microcarriers. However, as set forth above, designating the microspheres of Devin et al as microcarriers does not make the microcarriers of the claims different from the microspheres. There is nothing in the claims to require the
15 microcarriers of the claims to be physically and/or chemically different from the microspheres. Since the scaffold of claim 1 is not different, as claimed, from the aggregated microspheres of Devin et al, the claimed scaffold does not circumvent limitations associated with static three-dimensional culturing methods.

20 ***Conclusion***

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In
25 the event a first reply is filed within TWO MONTHS of the mailing date

Art Unit: 1651

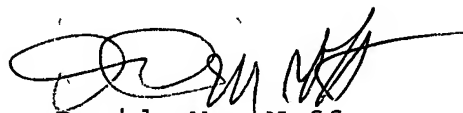
of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be
5 calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff
10 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this
15 application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN

3/25/05